

U.S.S.N. 10/053,929

Filed: January 22, 2002

**AMENDMENT AND RESPONSE TO OFFICE ACTION****Remarks****Rejection Under 35 U.S.C. § 103**

Claims 16-21 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,976,574 to Gordon ("Gordon") in view of U.S. Publication No. 2001/0018072 to Unger ("Unger"). Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

***Gordon***

Gordon discloses forming a powder by solubilizing a hydrophobic drug in an organic solvent, adding a hydrophilic excipient which is sparingly soluble or insoluble in the organic solvent, then spray drying the mixture to form a powder with a hydrophilic core surrounded by a hydrophobic drug coating (col. 8, lines 38-40). The drug coating is used to help prevent aggregation of the powder particles (col. 8, lines 40-55). Because it is hydrophobic, the coating repels water and prevents dissolution of the drug. Gordon does not disclose using a volatile pore forming agent. Further, Gordon's method does not form a porous drug matrix.

***Unger***

Unger describes a solid porous matrix containing a surfactant and a bioactive agent. In one embodiment, the matrix is formed by spray drying a solvent, surfactant, therapeutic agent, and blowing agent (para. 0076). The therapeutic agent is not dissolved in the solvent, as required by the claims, rather it is suspended since it is "only marginally soluble in the solvent." (para.

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0075). The only blowing agent disclosed by Unger is a liquid blowing agent, methylene chloride, which is not a volatile solid (see para. 0022).

***The combined references***

There is no teaching or suggestion in Gordon or Unger to combine these references. Gordon and Unger are directed at two different methods for producing two different types of particles. Gordon's method produces solid particles, while Unger's method produces porous particles. Gordon's method involves selecting a solvent in which the hydrophobic drug will fully dissolve (see Gordon, col. 8, lines 32-34). In contrast, Unger's method selects a solvent in which the drug is barely soluble (see Unger, para. 0075). Therefore Gordon contains no teaching or suggestion to combine its disclosure with Unger's.

Even if one of ordinary skill in the art combined Gordon with Unger, the claimed methods would not be obvious to one of ordinary skill in the art. Neither reference discloses the claimed method. Neither reference discloses using a volatile solid pore forming agent, as required by the amended claims. Support for the amendment to claim 16 can be found in the specification at least at page 3, line 30 and page 20, line 11. Therefore the claimed methods for making pharmaceutical compositions are not obvious in view of the combination of Gordon with Unger.

**Double Patenting Rejection**

Claim 18 was rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No. 6,395,300 to Straub et al.

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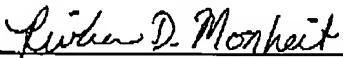
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("Straub"). In response, Applicants submit a terminal disclaimer to overcome this double patenting rejection.

Allowance of claims 16-21, as amended, is respectfully solicited.

Respectfully submitted,

  
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